UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/511,441	05/03/2005	Tomoji Maruyama	Tomoji Maruyama 260364US90PCT			
	7590 08/17/2007 AK, MCCLELLAND, MA	EXAM	EXAMINER			
1940 DUKE ST	TREET	YABUT, I	YABUT, DIANE D			
ALEXANDRIA, VA 22314			ART UNIT	PAPER NUMBER		
		3734				
		NOTIFICATION DATE	DELIVERY MODE			
		08/17/2007	ELECTRONIC			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com oblonpat@oblon.com jgardner@oblon.com

H

Office Action Summary		'	Application No.		Applicant(s)			
			10/511,441		MARUYAMA ET	AL.		
		1	Examiner		Art Unit			
			Diane Yabut		3734			
The MAI Period for Reply	LING DATE of this communic	cation appea	ars on the cover she	et with the c	orrespondence a	ddress		
WHICHEVER IS - Extensions of time if after SIX (6) MONT - If NO period for rep - Failure to reply with Any reply received	O STATUTORY PERIOD FO S LONGER, FROM THE MA may be available under the provisions of HS from the mailing date of this commu- y is specified above, the maximum state in the set or extended period for reply we by the Office later than three months aft adjustment. See 37 CFR 1.704(b).	ALLING DAT of 37 CFR 1.136(unication. utory period will vill, by statute, ca	TE OF THIS COMM (a). In no event, however, m apply and will expire SIX (6) ause the application to become	UNICATION hay a reply be time MONTHS from the ABANDONE!	L. ely filed the mailing date of this of (35 U.S.C. § 133).			
Status								
1) Responsi	ve to communication(s) filed	d on <u>11 Apri</u>	il 2007.					
2a) This actio	n is FINAL . 2	b)⊠ This a	ction is non-final.					
3) Since this	application is in condition f	or allowanc	e except for formal	matters, pro	secution as to th	e merits is		
closed in	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Cla	ms							
4) Claim(s)	1-8,25 and 26 is/are pending	g in the app	lication.					
4a) Of the	4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.								
6) Claim(s)	6)⊠ Claim(s) <u>1-8,25 and 26</u> is/are rejected.							
7) Claim(s)								
8) Claim(s) are subject to restriction and/or election requirement.								
Application Paper	5							
9) The specif	ication is objected to by the	Examiner.						
10) The drawi	ng(s) filed on is/are:	a) accep	oted or b)□ objected	d to by the E	xaminer.			
Applicant r	nay not request that any objec	tion to the dr	awing(s) be held in ab	eyance. See	37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath o	or declaration is objected to	by the Exar	miner. Note the atta	ched Office	Action or form P	TO-152.		
Priority under 35 l	J.S.C. § 119		•					
a)∏ All b)	dgment is made of a claim f ☐ Some * c)☐ None of:				-(d) or (f)			
	1. Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No							
	3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.								
Attachment(s)								
1) Notice of Referen		FO 048\		view Summary r No(s)/Mail Da				
· = :	erson's Patent Drawing Review (Pasure Statement(s) (PTO/SB/08) Date	5) 🔲 Notic		atent Application				

Application/Control Number: 10/511,441

Art Unit: 3734

DETAILED ACTION

This action is in response to applicant's amendment received 11 April 2007.

The examiner acknowledges the amendments made to the specification.

Claim Objections

1. Claim 7 is objected to because of the following informalities: Lines 3-4 of Claim 7 read "for configured to stop" and should instead read --configured to stop--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 2-4 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon (U.S. Patent No. 5,364,408).
- Claim 2: Gordon discloses a body part (distal end of 2), with a predetermined length, having a rotary portion (near 14) and can be inserted into said tissue of said organism from a hole formed subcutaneously in a tissue membrane of an organism, two hollow needle members 10 accommodated in a portion, inside said body part, rearward from said rotary portion, a needle member operation portion (proximal of 10) for advancing said two hollow needle members toward said rotary portion from a side surface of said

Art Unit: 3734

body part (Figures 1B-1D), and two openings disposed at a rear portion of said body part (proximal end of 10) and communicating with an inside of said two hollow needle members, wherein said rotary portion has two needle member receiving portions for receiving a distal end of one of said hollow needle members and that of the other of said hollow needle members 10 respectively pressed out of said body part, and a connection duct (where suturing thread 4 is accumulated near 12) communication with said two needle member receiving portions, and a duct for a suturing thread 4 is formed in a range from one of said two openings to the other of said openings through an inside of one of said two hollow needle members, said connection duct, and an inside of the other of said two hollow needle members, when said two needle member receiving portions receive said hollow needle members respectively at a same time (Figure 1A). Claims 3-4 and 7-8: Gordon discloses a suturing member which can be inserted into said duct for a suturing thread, and said suturing member includes a guide portion linearly formed of an elastic material and a suturing thread portion provided on said guide portion and the rotary portion has a thread pull-out slit extending from an upper surface thereof and communicating with said two needle member receiving portions and said connection duct (Figure 1A), an urging member for urging said needle member operation portion or said hollow needle member rearward and a stopper configured to stop said hollow needle members at a position pressed by said needle member operation portion, and an opening is formed at a rear end of said needle member operation portion (Figures 1B-1H).

Application/Control Number: 10/511,441 Page 4

Art Unit: 3734

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gordon** (U.S. Patent No. **5,364,408**).

Claims 25-26: Gordon discloses the claimed organism tissue suturing apparatus, as described above, which encompasses the same invention as the method steps including rotating the rotary portion in the tissue until the body part becomes oblique at a predetermined angle with respect to an axis of the rotary portion, returning the first hollow needle member and the second hollow needle member into the body part, returning the rotary portion to an initial position, and pulling out the organism tissue suturing apparatus out of the puncture site and leaving the suture thread (Figures 1A-1H), except for using the organism tissue suturing apparatus in a penetrated hole formed in a blood vessel. It would have been obvious to one of ordinary skill in the art at the time of invention to utilize the tissue suturing apparatus in a blood vessel, since Gordon discloses a method and device for approximating tissue, and it was well known in the art to occlude or approximate tissue in a vascular lumen or blood vessel to effectively suture a puncture or hole.

Art Unit: 3734

5. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (U.S. Patent No. 5,364,408), as applied to Claim 2 above, and further in view of Kortenbach (U.S. Patent No. 6,096,051).

Claims 5-6: Gordon discloses the claimed device except for a rotary portion towing wire which extends inside said body part and is fixed to said rotary portion at one end thereof, wherein said body part has a supporting pin for rotatably supporting said rotary portion, and said rotary portion having a side-surface opening, for receiving said supporting pin, formed long and axially extending to allow sliding of said supporting pin, a rotation angle restriction function permitting a rotation of said rotary portion between a state in which said rotary portion is on an approximate extension line of an axis of said body part and a predetermined angle less than 90 degrees.

Kortenbach teaches a rotary portion towing wire which extends inside said body part and is fixed to said rotary portion at one end thereof, wherein said body part has a supporting pin for rotatably supporting said rotary portion, and said rotary portion having a side-surface opening, for receiving said supporting pin, formed long and axially extending to allow sliding of said supporting pin, and a rotation angle restriction function permitting a rotation of said rotary portion between a state in which said rotary portion is on an approximate extension line of an axis of said body part and a predetermined angle less than 90 degrees (Figures 6D-6F). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a rotary portion towing wire and pin and a rotation angle restriction function, as taught by Kortenbach, to Gordon, since it was known in the art that the rotary portions commonly have pins for hinges to allow for

Art Unit: 3734

secure rotation as well as rotation restriction functions to avoid undesirable movement of the apparatus that may injure tissue.

Response to Arguments

6. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/511,441

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

MICHAEL J. HAYES

Page 7